

# CARES Act Amount Information Reporting: Entering Data Manually



## Reference Guide



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## Introduction

CARES Act Amount Information Reporting system is intended to provide a portal solution for all registrants or their authorized agents to submit reports on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution in compliance with section 3112(e) of the Coronavirus Aid, Relief, and Economic Security Act.

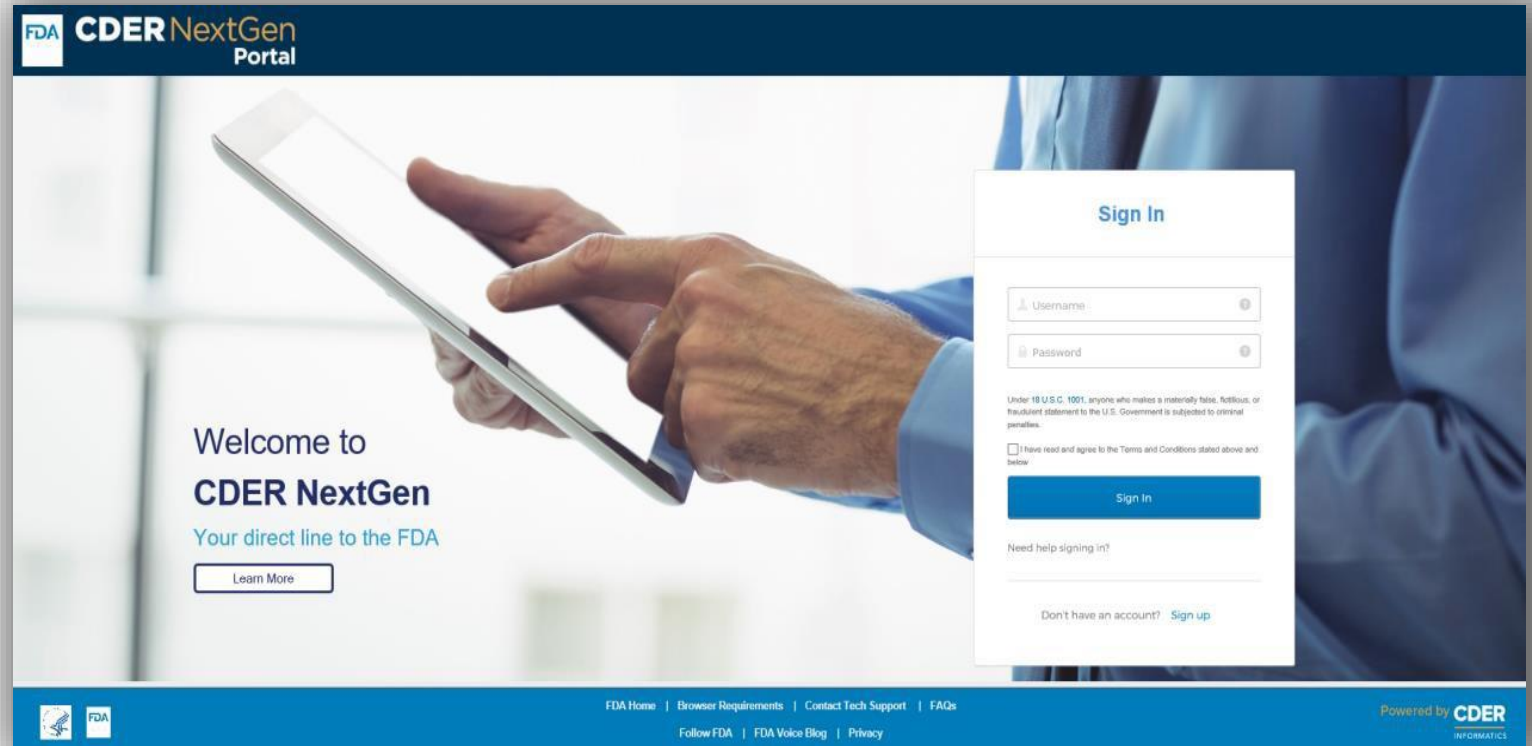
This guide describes how to use the CDER NextGen Portal to **manually enter data** to create and submit a CARES Act Amount Information report to the FDA. It is an expanded version of the original **CARES Act Amount Information Reporting** guide posted on **the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts** webpage (<https://www.fda.gov/drugs/drug-shortages/coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts>).

For technical assistance, please email the EDM Support Team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)).

For questions on how to enter or upload data, please email the Drug Amount Reporting Team ([DrugAmountReporting@fda.hhs.gov](mailto:DrugAmountReporting@fda.hhs.gov)).

## CDER NextGen Portal Homepage

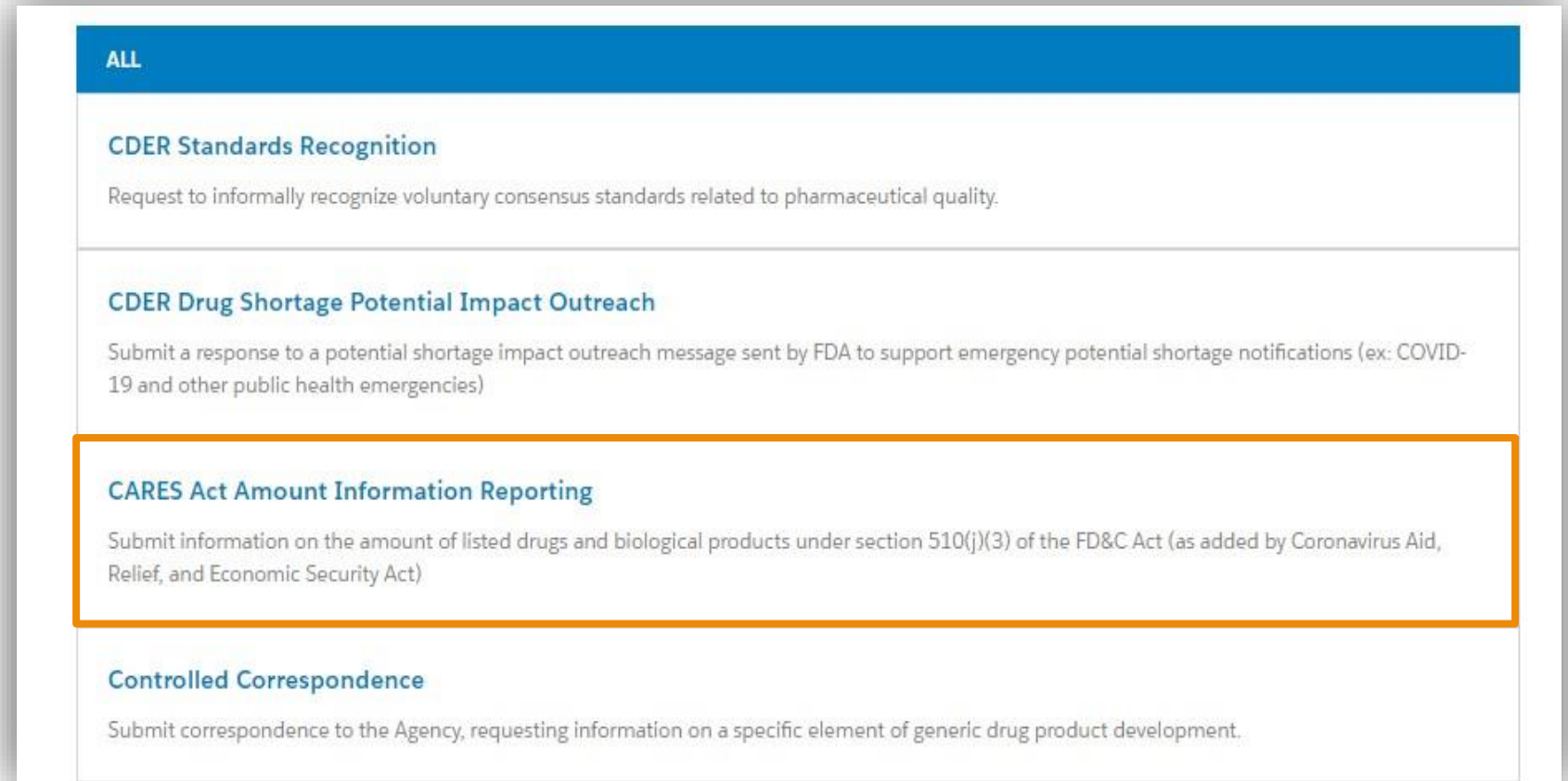
**Step 1.** First, sign in on the CDER NextGen Portal homepage.



# CARES Act Amount Information Reporting

## CDER NextGen Portal Homepage

**Step 2.** From the main menu, click **CARES Act Amount Information Reporting**.



# CARES Act Amount Information Reporting

## CARES Act Amount Information Report

**Step 3.** The next screen is the landing page. Draft reports and submitted reports appear here. Click **+ New Report** at the top right of the screen.


### CARES Act Amount Information Reporting

[00020506](#)  
Draft  
Last Modified: 11/29/2021, 04:48 PM  
Reporting Year: 2020

[00020357](#)  
Draft  
Last Modified: 11/29/2021, 04:48 PM  
Reporting Year: 2021

**CDER**NextGen  
Portal

## CARES Act Amount Information Reporting



### No CARES Act Volume Reporting Yet

Submit a new submission using the "+ New Report" button at the top right of your screen.

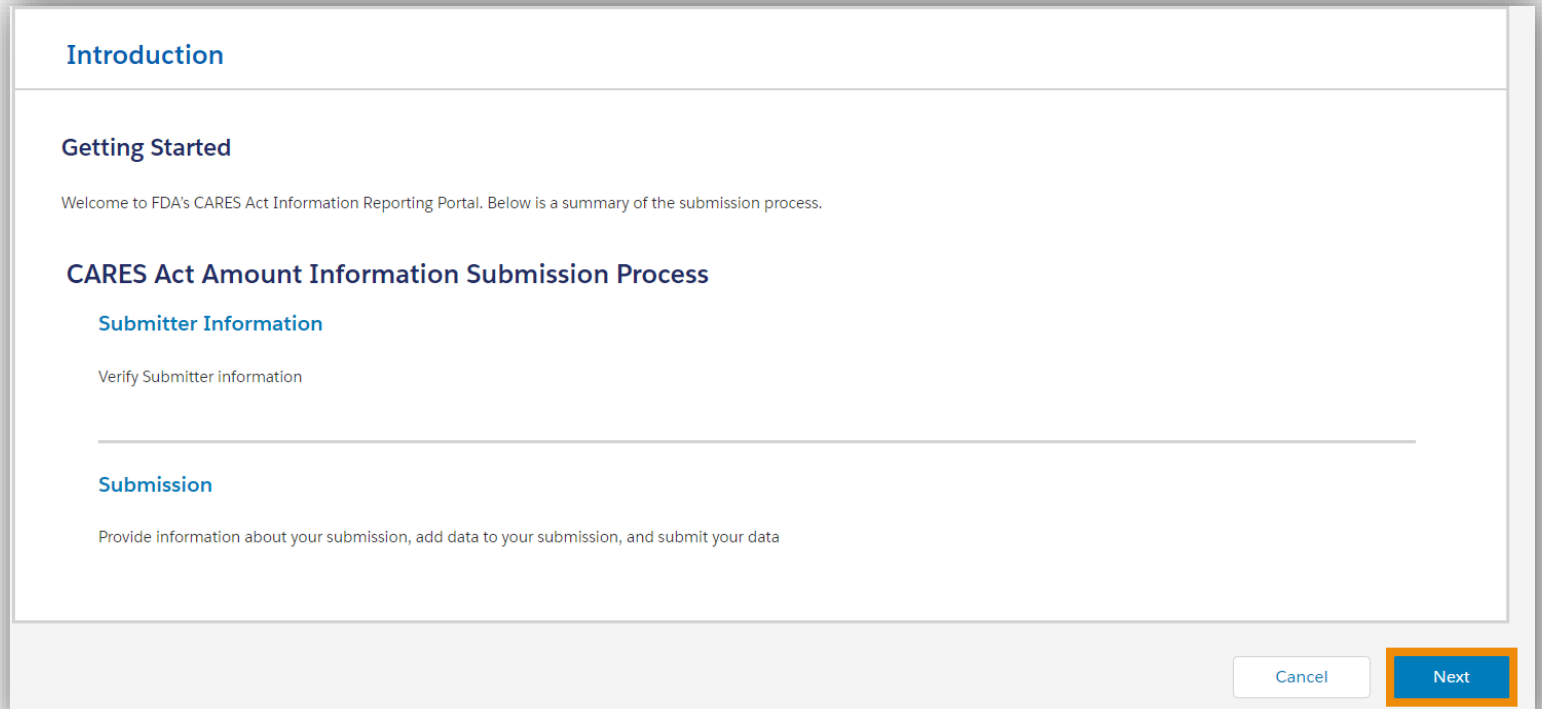
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INFORMATICS

## CARES Act Amount Information Report

**Step 4.** On the **Introduction** screen, review the **Getting Started** information for submitting a CARES Act Amount Information Report. Section descriptions of the submission process are displayed.

**Step 5.** Click **Next**.



The screenshot shows the 'Introduction' screen of the CARES Act Amount Information Reporting Portal. The page has a white background with a light blue header bar containing the word 'Introduction'. Below the header, the 'Getting Started' section is visible, which includes a welcome message and a summary of the submission process. The 'CARES Act Amount Information Submission Process' section is also displayed, with a link to 'Submitter Information' and a description of the submission process. At the bottom right of the screen, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted with an orange border.

**Introduction**

**Getting Started**

Welcome to FDA's CARES Act Information Reporting Portal. Below is a summary of the submission process.

**CARES Act Amount Information Submission Process**

[Submitter Information](#)

Verify Submitter information

**Submission**

Provide information about your submission, add data to your submission, and submit your data

[Cancel](#) [Next](#)

# CARES Act Amount Information Reporting

## Submitter Information

**Step 6.** On the **Submitter Information** screen, select if you are submitting as a **Registrant** or **Authorized Agent**.

**Step 7.** Review the prepopulated information in the **Profile Information** section, and then click **Next**. Contact technical support if any fields need to be updated.

### Submitter Information

Submitter Information

\* Are you submitting as a Registrant or an Authorized Agent?

☒ Registrant

☐ Authorized Agent

Profile Information

First Name

Last Name

Email Address

Phone Number

Extension

Organization Name

Address Line 1

Address Line 2

City

State/Province

Zip Code

Country

Save

Next



# CARES Act Amount Information Reporting

## Submission

**Step 8.** In the **Submission** screen, select the **year** (calendar year) that the report will cover.

**Step 9.** If you are submitting a replacement report to a previous submission, check **Yes**. Then, select the report ID of the previous submission from the drop-down menu.

**Step 10.** Select that you would like to submit product data **Manually**.

**Step 11.** In the confirmation screen, click **Continue**.

The screenshot shows the 'Submission' screen with the following fields and options:

- Submission Information**
- \* What year are you submitting for?**: A dropdown menu with '2021' selected.
- Are you submitting a replacement report to a previous submission?**: A checkbox labeled 'Yes' is checked.
- \* Please select the previous submission for which you are submitting a correction report.**: A dropdown menu with '00019877' selected.
- Date Submitted**: 9/21/2021, 04:34 PM
- \* Would you like to submit products manually or by uploading data from a csv file?**: Two radio buttons, 'Manually' and 'CSV File', with 'Manually' selected.
- Buttons**: 'Previous' (disabled), 'Delete' (red), 'Save' (blue), and 'Validate' (disabled).

The screenshot shows the confirmation screen with the following text and buttons:

**CARES Act Amount Information Report**

You are submitting a **CARES Act Amount Information Replacement Report** to a previous submission. Please note, by selecting a **Replacement Report** your previous submission will be replaced. Select Continue to proceed with the selected data submission method and submission type. After selecting Continue, you will not be able to change these selections. If a change is a required, or you do not intend to submit a **CARES Act Amount Information Replacement Report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

**Buttons**: 'Cancel' (disabled) and 'Continue' (blue).

## Submission

**Step 12.** To begin to submit product data manually, select **Add Establishment** to enter a DUNS Number.

Submission

Submission Information

\* What year are you submitting for?

2021

Are you submitting a replacement report to a previous submission?

☒ Yes

\* Please select the previous submission for which you are submitting a correction report.

00019877

Date Submitted: 9/21/2021, 04:34 PM

\* Would you like to submit products manually or by uploading data from a csv file?

☒ Manually

☐ CSV File

+

Add Establishment

Previous

Delete

Save

Validate

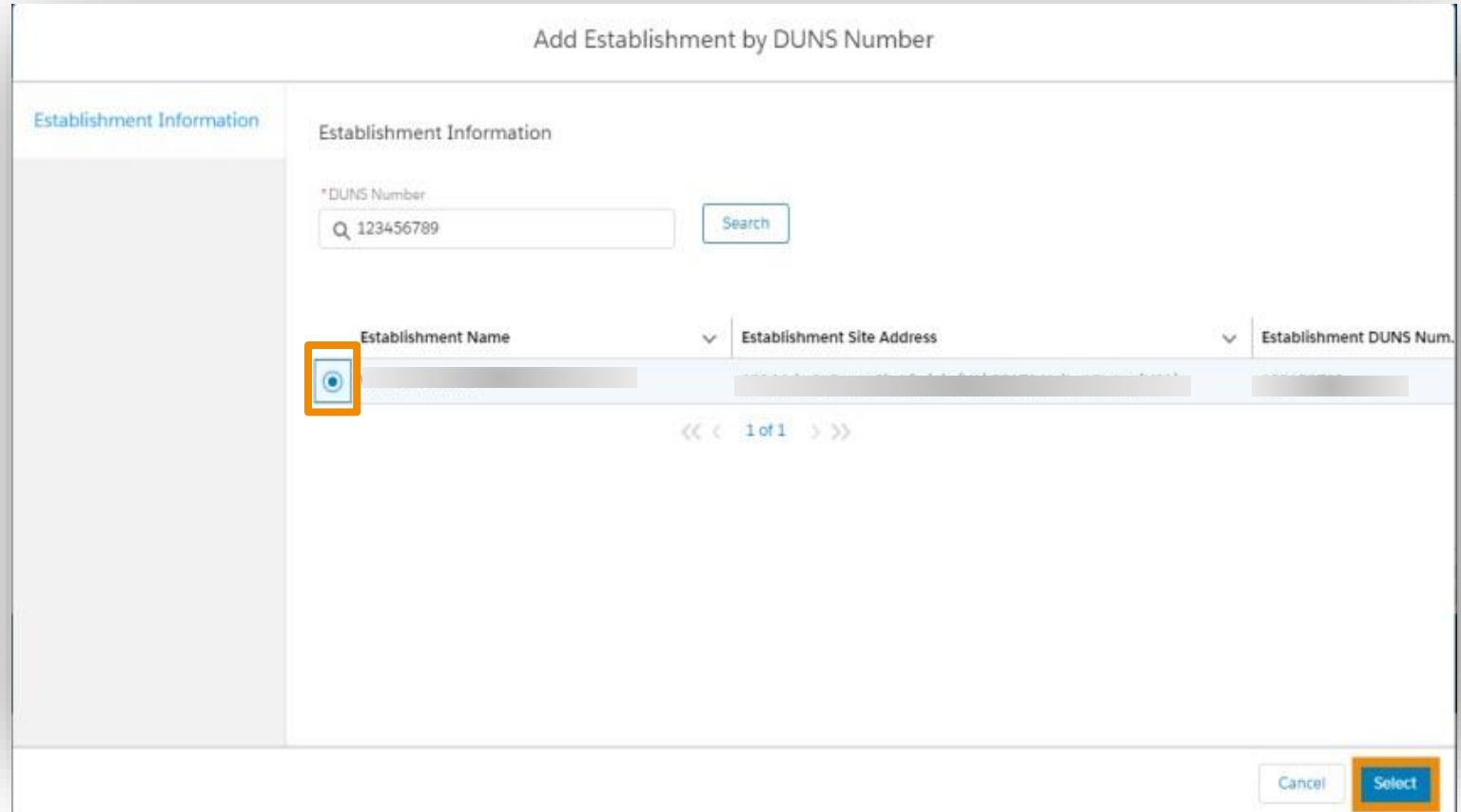
## Submission

**Step 13.** On the next screen, enter the 9-digit **DUNS Number** and click **Search**. If necessary, add leading zeroes.

If the search for a DUNS number succeeds, the name and address of the matching establishment is displayed.

If this is the correct establishment, click in the radio button on the left and then click **Select**.

If a different establishment is displayed, check that the DUNS number was correctly entered.



Add Establishment by DUNS Number

Establishment Information

\*DUNS Number  
Q 123456789 Search

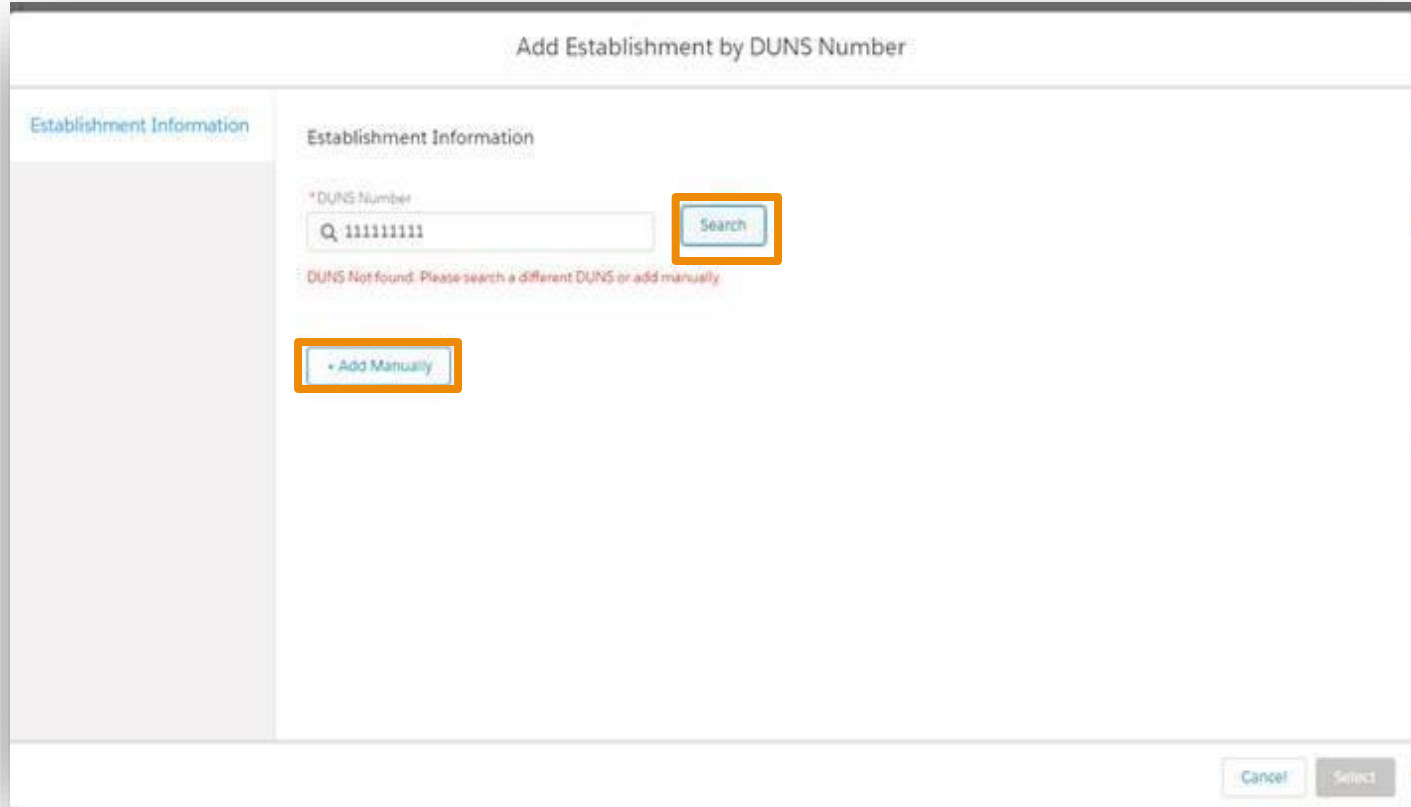
Establishment Name	Establishment Site Address	Establishment DUNS Num.
<input checked="" type="radio"/>		

<< < 1 of 1 > >>

Cancel Select

## Submission

**Step 14.** If the search for a DUNS number fails, an error message and an **+Add Manually** button will appear. Click the button to enter establishment information.



The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the label "Establishment Information". The main content area is also titled "Establishment Information" and contains a search field labeled "\* DUNS Number" with the text "111111111" entered. To the right of the search field is a "Search" button. Below the search field, a red error message reads "DUNS Not found. Please search a different DUNS or add manually." Below this message is a button labeled "+ Add Manually". At the bottom right of the form are "Cancel" and "Select" buttons. Orange boxes highlight the "Search" button, the error message, and the "+ Add Manually" button.

# CARES Act Amount Information Reporting

## Submission

**Step 15.** When **+Add Manually** is clicked, a screen for manually entering establishment information appears.

Enter the requested information and then click **Save**.

The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the link "Establishment Information". The main content area is titled "Manually Add Establishment Information". It contains several input fields, each with an asterisk indicating it is required:

- \* Establishment DUNS Number: A text input field with a "Back to Search" button to its right.
- \* Establishment Name: A text input field.
- \* Address Line 1: A text input field.
- Address Line 2: A text input field.
- \* City: A text input field.
- \* Country: A dropdown menu currently showing "--None--".
- State/Province: A text input field.
- \* Zip Code: A text input field.

At the bottom right of the form are two buttons: "Cancel" and "Save". The "Save" button is highlighted with an orange border.

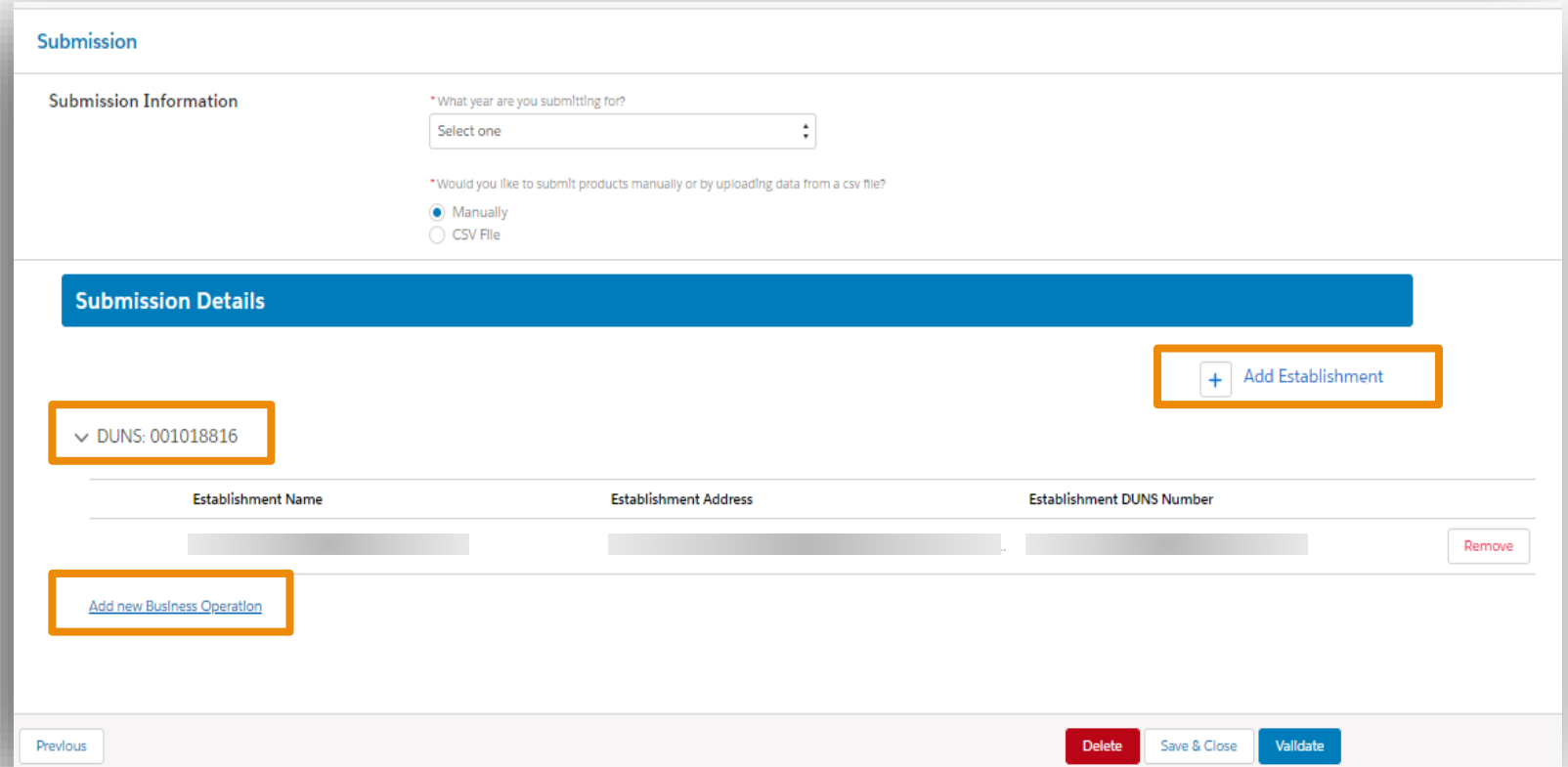
## Submission

**Step 16.** After a DUNS number is selected, the Submission screen opens.

Click the arrow next to the DUNS number or click on the DUNS number to expand its entry. Establishment information will be displayed.

Then, click on **Add New Business Operation**.

To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



The screenshot shows the 'Submission' screen. At the top, there's a 'Submission Information' section with two dropdown menus: 'What year are you submitting for?' (set to 'Select one') and 'Would you like to submit products manually or by uploading data from a csv file?' (with 'Manually' selected). Below this is a blue bar labeled 'Submission Details'. Underneath, there's a dropdown menu for 'DUNS: 001018816'. To the right of this is a button labeled '+ Add Establishment'. Below the DUNS dropdown is a table with three columns: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. The table is currently empty. Below the table is a button labeled 'Add new Business Operation'. At the bottom of the screen, there are four buttons: 'Previous', 'Delete', 'Save & Close', and 'Validate'.

# CARES Act Amount Information Reporting

## Submission

**Step 17.** Select an option from the drop-down menu of Business Operations. Each Business Operation can be selected only once, and in any order. Each DUNS can have one Business Operation or multiple Business Operations. There is a **Remove** button next to each DUNS number and Business Operation, if needed.

**Step 18.** Click **+Add Product** to add a product. Each Business Operation can have one product or multiple products.

The screenshot displays the 'Submission Details' form. At the top right is a '+ Add Establishment' button. Below it, a collapsed section 'DUNS: 123456789' is shown. A table with three columns: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number' is present. The first row has empty input fields and a 'Remove' button. Below the table, a label '\* Select the Business Operation.' is followed by a dropdown menu currently showing 'Select one'. The dropdown list includes 'API Manufacture', 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. A 'Remove' button is next to the dropdown. To the right of the dropdown is a '+Add Product' button. At the bottom left is a 'Previous' button, and at the bottom right are 'Delete', 'Save', and 'Validate' buttons.

# CARES Act Amount Information Reporting

## Submission

**Step 19.** Clicking on **+Add Product** opens a screen to enter an NDC. Enter the **NDC** of the product and then click **Search**.

If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

If the search fails, and you know the NDC number to be correct, click **+Add Manually**.

SEARCH RESULTS

NDC

1546-0010-12

Allowable formats are: 1234-1234-12, 12345-123-12, and 12345-1234-1

Search

+ Add Manually

Add Drug or Biological Product by NDC

	NDC
<input checked="" type="checkbox"/>	1546-0010-12

Cancel Select



# CARES Act Amount Information Reporting

## Submission

**Step 20.** After clicking on **+Add Manually**, enter the NDC number and then click **Add Product**, which will return you to the **Submission** screen.

Add Drug or Biological Product Manually

\* NDC  
1234-1234-12

Back to Search

Allowable formats are: 1234-1234-12, 12345-123-12 and 12345-1234-1

Cancel Add Product

# CARES Act Amount Information Reporting

## Submission

Outermost Package				Innermost Package			
NDC	Quantity Released	Quantity Distributed (non-US)	Package Type	Quantity Released	Quantity Distributed (non-US)	Package Type	Market Unknown?
<input type="checkbox"/> 1234-1234-12	<input type="text" value="20"/>	<input type="text" value="10"/>	<input type="text" value="BOTTLE:"/>	<input type="text" value="20"/>	<input type="text" value="6"/>	<input type="text" value="BOTTLE"/>	<input checked="" type="checkbox"/>
<div>+Add Product</div>							<div>Remove Product</div>

**Step 21.** In the Submission screen, enter the requested amount information of the product and click each **pencil** to enter the package types. If a product has single-level packaging, use only the “Outermost Package” fields. Click **+Add Product** and/or **Remove Product** as needed. Select the checkbox under **Market Unknown**, if applicable.

Scroll to the right and click the arrow to expand the record so that data can be entered by month.

# CARES Act Amount Information Reporting

## Submission

**Step 22.** For each month, enter the amounts released or distributed. Use only whole numbers, no decimals or fractions.

Fields can be left blank for months during which the product was not released or distributed.

The top row, which contains the NDC number, also contains fields for annual totals. The annual total fields will automatically update when a monthly field is updated. Also, annual totals can be entered directly into the top row.

August	8	55.6	8	
September	90	76	3	99
October	10	34	100	
November	11	2	11	
December	12	56	122	
<input type="checkbox"/> 0002-3237-04    0    0    SYRINGE    7    32,561    Sel <input type="checkbox"/>				
January				
February				33
March			3	
April				

# CARES Act Amount Information Reporting

## Submission

**Step 23.** Data will be validated before a report can be submitted.

When all data has been entered, click **Save**. The system requires saving the report at least once before validation.

**Step 24.** In the confirmation window, click **Save** to stay on the Submission page or click **Save & Close** to go to the landing page.

On the landing page, select the newly created and saved report to return to it.

The screenshot shows the 'Submission Details' form. At the top, there's a blue header with the title. Below it, a dropdown menu shows 'DUNS: 123456789'. The form is divided into sections for 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. The DUNS number is pre-filled as '123456789'. Below this, a section titled '\* Select the Business Operation.' has a dropdown menu set to 'Manufacture'. The main part of the form is a table with columns for 'Outermost Package' and 'Innermost Package'. The 'Outermost Package' section has a checkbox for 'NDC', a dropdown for 'Quantity Released' (set to '1,200'), a dropdown for 'Quantity Distributed (non-US)' (set to '2,400'), and a dropdown for 'Package Type' (set to 'CASE'). The 'Innermost Package' section has a checkbox for 'Market Unknown?' (set to 'No') and a dropdown for 'Quantity Released' (set to '1,200'). At the bottom, there are three buttons: 'Previous', 'Delete', and 'Save & Validate'.

Establishment Name	Establishment Address	Establishment DUNS Number
		123456789

\* Select the Business Operation.

Manufacture

Outermost Package				Innermost Package			
<input type="checkbox"/> NDC	Quantity Released	Quantity Distributed (non-US)	Package Type	<input type="checkbox"/> Market Unknown?	Quantity Released	Quantity Distributed (non-US)	Package Type
<input type="checkbox"/> 0093-4231-01	1,200	2,400	CASE	<input type="checkbox"/>	1,200	2,400	CASE

Previous Delete Save & Validate

The screenshot shows the landing page of the CARES Act Amount Information Reporting system. At the top, there's a blue header with the title and a '+ New Report' button. Below the header, there's a search bar with the text 'Search Submissions' and a 'Search' button. Below the search bar, there's a list of reports. The first report is highlighted with an orange border and contains the following information: '00027055', 'Draft', 'Last Modified: 03/03/2022, 01:06 PM', 'Reporting Year:', and 'Unsubmitted Draft'.

CARES Act Amount Information Reporting + New Report

Search Submissions Search

00027055  
Draft  
Last Modified: 03/03/2022, 01:06 PM  
Reporting Year:  
Unsubmitted Draft

The "Validated Successfully!" message means that validation occurred, not that all the data was found to be valid.

## Submission

**Step 25.** Click the **Validate** button at the bottom of the page.

**Step 26.** If the data has been validated, **Submit** will be active. After validation, the report can be saved or submitted. To submit the report, check the box in the **Certifications** section to affirm that the information you provided in this submission is correct and then click **Submit**.

Click **Save** to keep the report for later or click **Delete** to remove the submission.

**Step 27.** In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.

The screenshot displays the 'Submission' section of the CARES Act Amount Information Reporting interface. A 'Validated Successfully!' message is shown at the top. The 'Submission Information' section includes a dropdown for the submission year (2021), a checkbox for replacement reports (checked), a dropdown for previous submissions (00019877), and a date submitted (9/21/2021, 04:34 PM). Below this, there are radio buttons for submission method (Manually selected, CSV File). A blue bar labeled 'Submission Details' is present, followed by a '+ Add Establishment' button and a DUNS number (123456789). At the bottom, there are 'Previous', 'Delete', 'Save', and 'Validate' buttons. The 'Validate' button is highlighted with an orange box.

The 'Certifications' section is visible below, featuring a checkbox (checked) for affirming the information's correctness. Below this, a modal window titled 'Complete & Submit CARES ACT Amount Information Report' is shown, asking for confirmation to submit the report. The modal has 'Cancel' and 'Submit' buttons, with the 'Submit' button highlighted by an orange box. The main interface also shows 'Delete', 'Save', and 'Submit' buttons at the bottom, with the 'Submit' button highlighted by an orange box.

## Submission

**Step 28.** After clicking on **Submit**, there will be a confirmation screen to confirm your report was submitted to the FDA.

Click **Return Home** to log out or **New Report** to submit a new report.

### CARES Act Amount Information Report Submitted to the FDA

**Congratulations!**

00005218

Date/Time Submitted: 10/15/2021, 02:05 PM

Reporting Year: 2021

Your CARES Act Amount Information Report **#00005218** has been submitted successfully. If you need to make changes to your submission, please contact FDA Staff at ([DrugVolumeReporting@fda.hhs.gov](mailto:DrugVolumeReporting@fda.hhs.gov)) and include the Report ID.

[Return Home](#)[New Report](#)

For technical support, please contact the CDER platform support team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)).

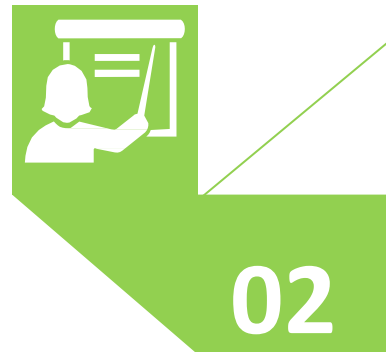
## Technical Support and Resources

# CDER NextGen Portal Support & Resources

The [CDER NextGen Portal](#) has many resources for support.

## CDER NextGen Portal Announcements

Your portal home page contains **portal announcements** so users are always in the know.



## Learn More Information

Everything related to the portal events can be found on the “**Learn More**” link. On the event home page, users can find the “Learn More” link to **Reference Guides and FAQs**.



## Technical Support

For all technical support, contact **CDER Platform Support Team** at [FDMSupport@fda.hhs.gov](mailto:FDMSupport@fda.hhs.gov).



## CDER NextGen Portal Video Tutorial

The “**Video Tutorial**” contains **1-4 minute video clips** on how to complete submissions for events on the portal.